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MAY 15 2009

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

   Medicomp, Inc.
   7845 Ellis Road
   Melbourne, Florida 32904

   Date Summary Prepared: March 12, 2009

   Contact: Mr. Michael Thomas

2. **Name of the Device:**

   Epicardia 5000

3. **Predicate Device Information:**

   K#900207, Epicardia 4000, Medicomp, Inc.

4. **Device Description:**

   The EPICARDIA System is a screening tool for patients who require ambulatory ECG monitoring for extended time periods. The system records and analyzes the patient's ECG, and provides various summary reports that detail any clinically-significant events the patient may have had, based on the EPICARDIA classifications. These reports are then reviewed, revised if necessary by a trained operator and then confirmed by a qualified clinician.

5. **Intended Use:**

   The EPICARDIA System is designed to acquire, store and analyze ECG signals from ECG electrodes on ambulatory patients. Epicardia is a software application that receives the data from patient monitors, provides user operations for editing the results of the analysis and then formats the data for printing.

   The system is to be used by a trained operator; the summary reports should be confirmed by a qualified clinician.

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6. Comparison to Predicate Device:

The following comparison chart outlines similarities and differences between the subject device and the predicate device:

Features	Predicate Device Epicardia 4000	Subject Device Epicardia 5000
ECG Analysis	Yes (Diogenes)	Yes (Diogenes SV)
User Interface	Personal Computer (DOS)	Personal Computer (Windows)
PC Interface	Direct USB File	TCP/IP Trans-telephonic Cellular Direct USB File
Operating System	MSDOS, Microsoft Windows	Microsoft Windows
EC38 Type	Type 3	Type 3

6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

All testing performed on the Epicardia 5000 was derived from the risk assessment which evaluated the effects of the feature changes. Testing included software validation testing.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The subject device, Epicardia 5000, has identical indications for use as the predicate device, Epicardia 4000. The bench testing contained in our submission demonstrates that there are no differences in their technological characteristics, thereby not raising any new issues of safety or effectiveness. Thus, the Epicardia 5000, is substantially equivalent to the predicate device, the Epicardia 4000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2009

Medicomp, Inc.
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, NY 11021

Re: K090834
Trade/Device Name: Epicardia 5000
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class II (two)
Product Codes: DSI
Dated: April 23, 2009
Received: April 24, 2009

Dear Ms. Goldstein-Falk:

This letter corrects our substantially equivalent letter of May 15, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

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510(k) Number (if known): K090834

Device Name: Epicardia 5000

Indications For Use:

The Epicardia 50000 system is indicated as a screening tool for patients who require ambulatory ECG monitoring for extended time periods. The system records and analyzes the patient's ECG, and provides various summary reports that detail any clinically-significant events the patient may have had, based on the EPICARDIA classifications. These reports are then reviewed, revised if necessary by a trained operator and then confirmed by a qualified clinician.

Prescription Use X (Per 21 CFR 801 Subpart D) OR Over-The Counter Use ___ (21 CFT 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090834